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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,080	01/04/1999	JANICE AU-YOUNG	PF-0066-2-DI	2905

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/09/2004

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/225,080

Applicant(s)

AU-YOUNG, JANICE

Examiner

Karen A Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40 and 42 is/are allowed.
- 6) ☒ Claim(s) 39 and 41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

1. After review and reconsideration, the Finality of the Office Action of the Paper mailed January 27, 2003, is withdrawn.
2. Claims 39-42 are under consideration.
3. Sections of Title 35, U.S. Code not found in this action can be found in a prior action.
4. Claims 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 39 is drawn in part to an amino acid sequence having at least 90% identity to the sequence of SEQ ID NO:2, wherein said amino acid sequence conserves amino acid residues of C23, C26, C41, C48, C69, C73 and N96 and is expressed on the surface of stem cells. Claim 41 is drawn to a pharmaceutical composition of the polypeptide of claim 39 and a pharmaceutically acceptable carrier.

The specification and claims as filed do not provide support for the specific limitation of an amino acid sequence having at least 90% identity to SEQ ID NO:2, or the conservation of amino acid residues of C23, C26, C41, C48, C69, C73 and N96 of SEQ ID NO:2. The specification states on page 4, lines 25-33 that a "variant of SCAH may have an amino acid sequence that is different by one or more amino acid "substitutions" and that said variant may have conservative changes and non-conservative substitutions. This does not provide support for a claim limitation of 90% sequence similarity to SEQ ID NO:2. The specification states on page 6, lines 15-19 that amino acid alignments between chicken stem cell antigen (GI 509840), Sca-2 (GI 434660), Mus musculus thymic shared antigen-1 related sequence pseudogene (GI 1199651), Scah-1 and Scah-2 exhibit conservation of amino acid residues of C23, C26, C41, C48, C69, C73 and N96. This does not provide adequate support for a variant of SEQ IDS NO:2 which exhibits conserved amino acid residues of C23, C26, C41, C48, C69, C73 and N96

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because the specification as filed did not contemplate this limitation for the disclosed variants. Further, claim 39 has been amended to delete reference to stem cells. The resulting amended claim is much broader in scope encompassing proteins expressed on other cell types not confined to the stem cell. This is not supported by the specification as filed which contemplates "novel human stem-cell antigen homologs" (page 5, lines 16-17). One of skill in the art would reasonable conclude that applicant was not in possession of the claimed invention.

5. Claims 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides comprising SEQ ID NO:2 and immunogenic fragments of SEQ ID NO:2, wherein said immunogenic fragments comprise at least 5 contiguous amino acids of SEQ ID NO:2 and are capable of generating an antibody that specifically binds to SEQ ID NO:2, does not reasonably provide enablement for an amino acid sequence having at least 90% identity to the sequence of SEQ ID NO:2 wherein said amino acid sequence conserves amino acid residues C23, C26, C41, C48, C69, C73 and N96 and is expressed on the surface of cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and the invention commensurate in scope with these claims.

Section b) and d) of claim 36 are dependent upon the identity of an amino acid sequence expressed on the surface of cells, wherein said amino acid sequence has at least 90 % sequence identity to SEQ ID NO:2 and conserves amino acid residues C23, C26, C41, C48, C69, C73 and N96. The requirements of 112, first paragraph state that one of skill in the art must be able to make and use the instant invention without undue experimentation. In order to fulfill the aforesaid claim limitations, one of skill in the art must first identify the sequence expressed on the surface of a cell; synthesizing an amino acid sequence having 90% identity to SEQ ID NO:2 with the conservation of amino acid residues of C23, C26, C41, C48, C69, C73 and N96 would not fulfill the limitations of the claim, because it is required that the sequence be expressed on a cell surface. The specification has not provided evidence that such a variant of SEQ ID NO: 2 exist in nature and is expressed on a cell surface. Reasonable correlation must exist between the scope of the claims and the enablement set forth, and given the lack of teaching in the specification, one of skill in the art would not be assured of being able to make and use the

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claimed variants of SEQ ID NO:2 because it is unknown if said variant having the recited characteristics exists in nature. Thus, one of skill in the art would be subjected to undue experimentation without reasonable expectation of success in order to make and use the broadly claimed polypeptides.

6. All other rejections and objections as set forth in the previous Office action are withdrawn.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

11/04/2004


KARENA CANELLA PH.D
PRIMARY EXAMINER